OMB No. 0990-0115

Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE http://www.niaid.nih.gov/contract/default.htm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.

RFP Number:	***Just In Time:***	Small Bus. Set-Aside [ ]Yes [X]No 8(a) Set-Aside [ ]Yes [X]No NAICS Code: 54171 Size Standard: 500 employees	***Level of Effort:*** [ ] Yes [X] No ***Total Effort:*** [N/A]
NIH-NIAID-DAIDS-02-07	[ ] Yes [X] No		

TITLE: HIV Vaccine Development Resources

Issue Date:	***Due Date:***	***Technical Proposal Page Limits:***
April 30, 2001	***Time:*** **July 6, 2001 4:00 PM, EST**	[X] Yes *(see "How to Prepare and Submit Electronic Proposals")* [ ] No

ISSUED BY:
Jacqueline C. Holden
Senior Contracting Officer
Contract Management Branch, DEA
NIH, NIAID
6700-B Rockledge Drive
Room 2230, MSC 7612
Bethesda, MD 20892-7612

[X] ***We reserve the right to make awards without discussion.***

NO. OF AWARDS:	***PERIOD OF PERFORMANCE:***
[ ] Only 1 Award [X] Multiple Awards	4 years beginning on or about 02/01/2002

Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. If your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR Clause 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation.

POINT OF CONTACT **-- Janet Mattson** ***--COLLECT CALLS WILL NOT BE ACCEPTED--***

Telephone: ***Direct*** **301-496-0993** ***Main*** **301-496-0612**	***Fax*** **301-480-5253**	***E-Mail*** **jm32u@nih.gov**

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BACKGROUND / STATEMENT OF WORK / NOTES TO OFFERORS

Background
HIV Vaccine Development Resources
DAIDS-02-07

The development of a vaccine to prevent the spread of HIV infection has been identified by the NIAID as a goal of the highest priority. While advances in immunology and molecular biology continue to offer an ever expanding array of approaches to the development of new candidates, the limited capacity to move promising concepts through the development process presents a substantial barrier to the full achievement of this potential. Limited industry involvement in key areas, especially international (non-clade B) vaccines, calls for a non-traditional, more active and developmentally oriented response by NIH and NIAID to meet the public health threat of the AIDS epidemic. Resources that could rapidly and efficiently close development and production gaps would greatly enhance the capacity to respond to emerging needs identified by NIAID and its advisory groups. The Vaccine Production Contract will support applied research that is not adequately being pursued by industry and will further develop leads derived from investigator-initiated research.

On October 15, 1998, RFP NIH-NIAID-DAIDS-99-21, entitled "HIV Vaccine Production," was issued for the purpose of obtaining vaccine production services, vaccine testing services, and FDA IND submission services. As a result of that solicitation, 14 contracts were awarded in July 1999. The RFP was resolicited in 2000 under RFP NIH-NIAID-DAIDS-01-06, entitled "HIV Vaccine Production, Pre-Clinical Testing, FDA Submission" and five additional awards were made in February 2000. Although some good vaccine candidates can be provided through these contracts, there are a number of promising vaccine candidates still available from various companies throughout the world to which the NIAID does not have access. In order to satisfy the initial "need" and to fill this void, the NIAID is resoliciting this effort through NIH- NIAID-DAIDS-02-07. The NIAID reserves the right to resolicit an RFP for these services in the future if it is determined necessary to fill the original “need."

INTRODUCTION

The objective of this Contract is to provide the NIAID a full range of developmental resources to bring a vaccine concept from the laboratory to initial human testing. It is envisioned that the ability to encourage and to support the development of multiple approaches will result in a shared knowledge base from which the best vaccine prototypes will emerge.

Vaccine Production: The area of work will require a product development team with the expertise to develop candidate vaccines, including scale-up and production of Good Laboratory Practices (GLP)/Good Manufacturing Practices (GMP) lots suitable for human use, and to perform the necessary characterization tests required for release of vaccines for clinical use. In some cases, a Task Order may support work on well-developed products that need only final steps in production, formulation and/or filling. Other Task Orders may involve very early and iterative steps in the development process and require several years of effort.

Under the Contract various Categories of vaccine will be developed based on: (a) recombinant proteins, (b) DNA vaccines, (d) vector based vaccines (virus, bacterial), (d) virus-like particles. Offerors may submit proposals based on their ability to perform scale-up and production of any one or more of these vaccine Categories.

CONTRACT TYPE

It is anticipated that multiple awards will be made for this Indefinite Delivery/Indefinite Quantity (ID/IQ) Solicitation. The Contract will be in effect for four (4) years. An ID/IQ Contract provides for an indefinite quantity, within stated limits, of supplies or services to be furnished during a fixed period, with deliveries or performance to be scheduled by placing orders with the Contractor. Task orders will be issued to the prequalified pool of Contractors based on the specific requirements of the Task Order.

Offerors may submit proposals for any one or more of the vaccine Categories. Proposals will undergo peer review based on the evaluation criteria and awards will be made to the most qualified proposals. Each Offeror awarded a Contract will receive a guaranteed minimum dollar award of $200,000 for the first year of the Contract. A single minimum award will be made per Contractor even if more than one Category is submitted.

It is anticipated that the maximum total funding under this Contract will be between $5 – 10 million per year. When a need is established for any of the products or services under this Contract, a Task Order will be submitted to one or more Contractor(s) qualified under that Category. Contractor(s) will submit a detailed proposal with milestones to perform the work stated in the Task Order together with a detailed budget proposal within 35 calendar days. Resulting awards will include specifics on deliverables and reports.

DEFINITIONS

Indefinite-Quantity Contract - FAR 16.504 defines an indefinite-quantity contract as a contract that provides for an indefinite quantity, within stated limits, of supplies or services to be furnished during a fixed period, with deliveries or performance to be scheduled by placing orders with the contractor.

Under an indefinite-quantity contract, the Government's agreement to order the minimum quantity provides the consideration necessary to bind the contractor to furnish additional quantities, which the Government may, but is not required to, order.

Task and delivery order contracting is authorized for use with indefinite-quantity contracts as described in FAR 16.504.

Task Order Contract - FAR 16.501-1 defines a task order contract as a contract for services that does not procure or specify a firm quantity of services (other than a minimum or maximum quantity) and that provides for the issuance of orders for the performance of tasks during the period of the contract.

FAIR OPPORTUNITIES TO BE CONSIDERED PROCESS

When the government develops a task order requirement, it will prepare a "Task Order Request" (TOR) for the purpose of soliciting proposals and selecting the most advantageous offer from among the multiple contract awardees.

Normally, each awardee will receive an opportunity to submit a proposal for those task order requests solicited under vaccine production, for which they received a contract. However, the Contracting Officer need not contact each of the multiple awardees before selecting a task order source if the Contracting Officer has sufficient information available to ensure that each awardee receives a fair opportunity to be considered for the task order.

Further, awardees need not be given an opportunity to be considered for a particular order in excess of $2,500 if the Contracting Officer determines that:

(i) The agency need for the supplies or services is of such urgency that the normal solicitation and evaluation process would result in unacceptable delays;

(ii) Only one such contractor is capable of providing such supplies or services at the level of quality required because the supplies or services ordered are unique or highly specialized;

(iii) The task order needs to be issued on a sole-source basis in the interest of economy and efficiency as a logical follow-on to a task order already issued under the contract, provided that all awardees which were qualified under the specific vaccine production for which the task order request covers were given a fair opportunity to be considered for the original task order request solicited; or

(iv) It is necessary to award the task order to a specific contractor to satisfy the minimum guarantee provision in its contract.

TASK ORDER PROCEDURES

In providing services under the contract, the following procedures shall apply to the award of task orders.

All work required under the contract shall be authorized through the execution of a bilateral task order. Each task order will obligate the necessary funds to complete the required task and will include the work statement of the task order as an attachment. Task orders may be issued at any time within the contract period. Subject to the exceptions described under

"Fair Opportunity To Be Considered Process" above, when the Government elects to fill a requirement that is estimated to exceed $2,500, the Contracting Officer shall provide a TOR to the awardees that received contracts for the vaccine production for which responses are being solicited. A TOR shall, at a minimum, include a Statement of Work, evaluation factors, specific reporting requirements, deliverables and delivery schedule, the relevant importance of technical and cost factors, and any special instructions.

Business proposals shall include direct and indirect costs necessary for performing the proposed task. Task order proposals shall generally be limited to a total of 20 pages, including attachments.

Within the time allowed for proposal preparation (time allowed for proposal preparation and submission will vary depending on the task), which will be designated in the task order request, Contractors shall submit their proposals in response to a task order request, which shall include, but not necessarily be limited to the following information:

(i) A statement of the contractor's clear understanding of the task requirements;

(ii) A statement of technical and managerial resources and expertise the contractor can provide to satisfy the requirement;

(iii) An approach to perform the work;

(iv) The labor category necessary, and the numbers of hours for each labor category necessary, and an explanation of the rationale for determining hours;

(v) Resumes with identification of the actual personnel proposed for the work;

(vi) A schedule of performance identifying major milestones, deliverables and delivery date, and task completion; and

(vii) an itemization of all costs, both direct and indirect, (i.e. personnel, fringe benefits, equipment, travel, supplies, other direct costs, overhead, etc.) necessary to complete the work.

The Government will evaluate proposals and conduct negotiations as necessary. Task orders will be awarded to the contractor whose proposal is determined to be the most advantageous to the Government based on the technical and price factors specified in the TOR. The Government reserves the right to make an award on the most favorable initial proposal without discussion.

The Contracting Officer is the only individual authorized to issue a TOR or award a task order under the contract. Unless specifically authorized by the Contracting Officer, the contractor shall not commence work on a requirement until a task order has been fully executed. It is anticipated that task orders will be awarded within 30 calendar days from receipt of task order proposals. Each task order shall, at a minimum, contain the following information:

- Date of order
- Contract number and task order number sequentially; e.g., N01-AI-12345 (Task order No. 01, 02, 03, etc).
- Description of services, and estimated cost.
- Performance period.
- Name and address of sponsoring office.
- Name of Contracting Officer's technical representative.
- Place of performance.
- Packaging, packing, and shipping instructions, if any.
- Accounting and appropriation data.
- Pricing Arrangements

  FAR 16.501-2(c) states that indefinite delivery contracts may provide for any appropriate cost or pricing arrangement under Part 16. Therefore, firm fixed price, cost reimbursement, time and materials, and labor-hour arrangements may be used.
- Any other pertinent information.

No protest under FAR Subpart 323.1 is authorized in connection with the issuance or proposed issuance of a task order under the contract except for a protest on the grounds that the order increases the scope, period, or maximum value of the contract. Task orders awarded under the contract are not subject to the competition requirements of FAR Part 6.

MINIMUM AND MAXIMUM QUANTITY OR DOLLAR VALUE

In response to this RFP, potential Offerors may submit proposals for requirements described in the Statement of Work (SOW). Proposals will undergo peer review based on the evaluation criteria and awards will be made to the most qualified proposals. Each Offeror awarded a contract will receive a guaranteed minimum dollar award for the first year of the Contract. The guaranteed minimum dollar award for Contractors will be $200,000 each. The maximum dollar value for the entire prequalified pool of Contractors for the four year period is $29,133,251.

LIMITATION ON PERIOD OF PERFOMANCE OF ORDERS

The clause at FAR 52.216-22, Indefinite Quantity, permits orders issued during the effective period of the contract, and not completed within that period, to be completed within the time specified in the order. The time specified in such orders, however, will not extend unreasonably beyond the contract expiration date.

TASK ORDER CONTRACT AND DELIVERY ORDER CONTRACT OMBUDSMEN

1. FAR 16.505(b)(4) requires that each agency designate a task order contract and delivery order contract ombudsman who will be responsible for reviewing complaints from contractors and ensuring that all contractors are afforded a fair opportunity to be considered for orders.

2. The Ombudsman for R&D task and delivery order contracts is Anthony Demsey, Ph.D. Correspondence from awardees on multiple award R&D task and delivery order contracts may be forwarded to the following address:

Dr. Anthony Demsey
Ombudsman for R&D Task and Delivery Order Contracts
c/o Ms. Zaiga Tums, Director, Division of
Acquisition Policy and Evaluation, OCM
Building 6100, Room 6C01
Bethesda, Maryland 20892-7540

Statement of Work
HIV Vaccine Development Resources
RFP DAID-02-07

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, directly or through subcontractors and/or consultants, as needed to undertake targeted research essential to translating basic research concepts into prototype vaccine products, under the direction of NIAID staff and as recommended by existing and ad hoc NIAID advisory groups.
[See NOTE #1 TO OFFERORS]

Specifically, the Contractor(s) shall:

1. Produce, scale-up, characterize and formulate specific vaccine products and reagents as directed by the Project Officer via a Task Order issued by the NIAID. Produce pilot lots of candidate vaccines under GLP/GMP appropriate for human clinical trials, at the direction of the Project Officer in one or more of the following vaccine Categories.

    a) Recombinant proteins
    b) DNA plasmid vaccines
    c) Vector-based vaccines [Viral, Bacterial]
    d) Virus-like Particles

2. Develop and manufacture specific vaccine products.
    [See NOTE #2 TO OFFERORS]

    a) Consult and coordinate with the product inventor throughout the development process. Complete a material transfer agreement, if needed.

    b) Develop detailed production plan and budgets for manufacture of lots of candidate vaccine products prior to undertaking GLP/cGMP production.

    c) Prepare, where applicable, master stocks, cell banks, bacterial or viral clones, etc.

    d) Purchase or subcontract, where applicable, products and materials necessary for vaccine production.

    e) Optimize expression in systems suitable for vaccine production and scale-up production to required capacity.

    f) Formulate (including adjuvant and excipients), vial, label, package, store and ship test lots of candidate products.

    g) Produce candidate vaccines in a form suitable for use in clinical trials (including characterization, formulation [including adjuvanting], vialing, labeling, packaging and storage). These products shall be prepared under GLP or cGMP conditions, as appropriate, by methods that meet FDA standards for products for human clinical trials as described in the Code of Federal Regulations, Title 21, Chapter I, Parts 58, 210 & 211, and 600-640 [April 1994] and the Guidelines on Sterile Drug Products Produced by Aseptic Processing [June 1987].

    h) Maintain an inventory of test and pilot lots of vaccine candidates that have been produced. Periodically, as required, examine titer or potency of vaccine products.

    i) Produce reagents necessary for the testing or evaluation of immune responses to vaccine products.

    j) Ship the manufactured, packaged, and labeled dosage forms utilizing shipping procedures and materials to maximize product stability.

    k) Manage and account for intellectual property rights that pre-exist or may develop through the activities of the Contractor, including maintenance of security of confidential and/or proprietary data.

3. Provide facilities, equipment and resources.

a) Receive, store and manipulate biohazardous materials (Biosafety Level 2 or 3 Containment as required) and maintain their viability in facilities which provide aseptic and/or sterile conditions as appropriate.

b) Maintain and operate controlled storage of samples at appropriate temperatures with appropriate monitoring for failure.

c) Provide facilities and equipment suitable for GLP/cGMP production of vaccine products.

d) Provide protective garments, equipment and sufficient monitoring to assure safe handling of potentially hazardous materials, including radioactive materials, for the safety and protection of workers.

e) Conduct work under this contract in accordance with all applicable and current Federal, state, and local laws, codes, ordinances and regulations, as well as all PHS Safety and Health provisions.

4. Perform vaccine lot characterization and stability tests.

At various steps during the manufacture of a vaccine the product must be characterized. Prior to use of a vaccine in clinical studies the manufactured vaccine will need to undergo final lot release testing. As described in the regulations for General Biological Product Standards (21 CFR 610) the following tests shall be performed for each lot of vaccine.

a) Test for Potency. A test for potency shall be performed. (A test for potency [21 CFR 610.10] will evaluate in an in vitro or in vivo test the specific ability of the vaccine to effect a given response, such as an immune response in mice, which should be supportive of the efficacy of the vaccine in humans. In the case of DNA vaccines potency may be evidenced by the production of the pertinent antigen in a transfected cell line).

b) Test for General Safety. The general safety test [21 CFR 610.11] shall be performed in mice and guinea pigs on each lot of vaccine to detect extraneous toxic contaminants potentially introduced during manufacture.

c) Test for Sterility. A test for sterility [21 CFR 610.12] shall be performed as described in the regulations.

d) Test for Purity. A test for purity [21 CFR 610.13] shall be performed on each lot to ensure that the product is free from extraneous material except for that which is unavoidable due to the manufacturing process. (In addition, the test for purity includes an evaluation of residual moisture and the presence of pyrogenic substances in the product.)

e) Test for Identity. A test for identity shall be performed. (The test for identity [21 CFR 601.14] is generally a physical or chemical test performed to establish the identity of the material in the final container.)

f) Test for Quantity. A test for quantity shall be performed. (A measure of the amount of material present is imperative for calculating the dilution of the bulk material required for the final container fill.)

g) All other tests as may be required for specific vaccine types. Develop and validate procedures as needed.

h) Perform stability testing.
[See NOTE #3 TO OFFERORS]

5. Provide all data, information and records required for the writing and submission of the Master File, Investigator's Brochure, and all other documents related to Investigational New Drug (IND) submission to the Project Officer or to a designated third party. Provide information pertaining to the composition, manufacture, and quality control of the vaccine product as appropriate for particular investigations to be covered by an IND.

6. Participate in discussions with the FDA during pre-IND and IND meetings.

7. Meet with the Project Officer at periodic intervals, to be scheduled after Contract award.

8. Retain all records, samples, histopathological slides, etc. as indicated under GLP and GMP guidelines and be able to make them available to the Project Officer or designee.

Notes To Offerors
HIV Vaccine Development Resources
DAID-02-07

NOTE #1 TO OFFERORS: All clinical trials involving these vaccine products will be performed under an IND held by the NIH or the vaccine sponsor and will include Institutional Review Board (IRB) approval and informed consent to limit liability of the manufacturer.

Since single institutions may not have the expertise and facilities required to perform work in all the vaccine Categories in the Statement of Work, it is acceptable for an Offeror to submit a proposal for any one or more vaccine Category. See evaluation criteria. Each vaccine Category will be independently evaluated so that the Offeror will only be evaluated based on the specific Category(s) for which they apply. Lack of expertise in one Category will not affect the evaluation of other Categories.

Offerors shall have a separate section for each Category, addressing the evaluation criteria and other requirements (methods, staff, experience, allocated facilities, etc.). Each Category will be evaluated (scored) individually so that an Offeror will be graded and determined to be Qualified/Not Qualified for each Category independently, based on the evaluation criteria for each Category. The submission format should allow all the information needed to evaluate each Category to be dissected free of that which pertains to other Categories. There can be core sections (e.g., personnel, facilities, resources, etc.) which are the same for all Categories but which are referenced specifically under the section for each Category.

If the Offeror wishes to include in the proposal Categories or specific tasks for which it does not have direct expertise, then the Offeror may propose a subcontractor in order to fulfill the requirements. The Contractor shall be directly responsible for all work performed under this Contract, including work done by any subcontractor. The Offeror shall describe in the technical proposal, areas of responsibility of any subcontractor as they pertain to the Work Statement in the same detail as their own proposal.

To perform activities described in this RFP, a highly qualified and experienced product development team consisting of Research Scientists and Technicians is required. The Principal Investigator will be responsible for overall management and productivity of all activities for a given Category. Offerors must be experienced and qualified for GLP/cGMP production.

Technical proposals must describe specifically how the Offeror will fulfill each of the items in the Statement of Work.

The technical proposal shall include:

- qualifications, experience, and specific assignment of each proposed member of the research team (include resumes/CVs); how they will interact regarding lines of authority (provide an administrative framework in flow chart format); the decision-making authority of the Principal Investigator in relation to the rest of the organization

- specific levels of effort proposed for each individual (hours/percentages of time) and availability in relation to other commitments

- procedures for initiation of this Contract's projects in a timely manner (describe how other projects in general are prioritized within their organization and the level of priority this Contract will receive)

- all instrumentation, equipment, and laboratory space to be used to fulfill the work requirements (indicate what equipment and resources are under the control of the Principal Investigator and which are to be shared; if shared, indicate who is responsible for controlling access and how determination of priority usage is made)

- a production plan with milestones and a time line. The contract may provide incentives (including fee incentives) for meeting or penalties for not meeting the milestone schedule.

The number and types of products to be developed cannot be specified at this time. For the purposes of responding to this RFP, the Offeror shall describe in some detail its experience with the development/optimization of a specific vaccine, preferably a biologic product, regardless of the applicability of that particular product to an HIV vaccine.

In the proposal the Offeror shall demonstrate their degree of flexibility in their capability and willingness to produce a variety of different products within a vaccine Category as opposed to making only a single proprietary product. This may be accomplished by giving examples of how they have had the capacity to make multiple related products in the past or examples of the range of products they would be willing to make under this contract.

The intent of this description is to demonstrate to the reviewers of the proposal the capabilities and problem-solving experience of the Offeror during early developmental phases. The Offeror shall demonstrate understanding of the approach and establish their capacity for production and scale-up under GMP.

Since it is not expected that any one Offeror will have the capacity to develop or produce every Category of vaccine, the Offeror may submit a proposal for any one or more of the vaccine categories. Each Offeror will be evaluated based on the specific Category(s) of vaccine for which they apply. Thus, it is essential that the Offeror state the Category for which they are applying. The Offeror is requested to propose a detailed plan for producing a pilot lot through to the final form to be delivered for clinical trials of any one or more of the four vaccine Categories.

The Offeror shall submit a plan for each vaccine Category for which they are applying. If the Offeror does not have a specific vaccine to propose for production in one of these categories, they should use the examples below to construct a plan and proposed budget.

a) Recombinant protein – 1000 doses of rGP120, formulated with alum adjuvant at 200 ug/dose. Assume that the HIV strain is a primary NSI strain.

b) DNA vaccine – 1000 doses of a clinical grade recombinant plasmid with sequence(s) of relevant genes.

c) Vector-based vaccine. Live recombinant virus - 10,000 doses of recombinant vaccinia expressing an HIV env gene from one promoter and an HIV gag gene from another, to be delivered at 10^8 pfu/dose. Assume that the HIV inserts are stable, and the recombinant vector has shown good growth properties in a variety of standard mammalian cell substrates. (Alternatively, propose a bacterial vector based vaccine)

d) Virus-like particle – 1000 doses at 100 ug p24/dose.

For each vaccine Category, the Offeror shall propose production, purification and characterization methods and a timeline for obtaining completion of each pilot lot, with sufficient data generated for IND submission. Potential pitfalls and back-up plans shall be included. The Offeror shall include a statement of its maximum capacity for production of each vaccine lot. Include cost estimates in the form of a detailed budget proposal for performing all the activities listed in the Statement of Work.

When the need arises to issue a Task Order under this Contract, prequalified Contractor(s) will be requested to submit a detailed production plan and cost proposal for that specific task.

NOTE #2 TO OFFERORS: Such products may incorporate multiple components (e.g., genetic or phenotypic variants of HIV, various HIV gene products, immunomodulatory cytokines or the corresponding genes, third party adjuvants, delivery systems, etc.).

A single Task Order may include any or all of the work in the Work Statement. For example, a Task Order may be limited to the vaccine or reagent formulation (including adjuvant and excipients), vialing, labeling, packaging, storage and/or shipment of premanufactured products.

NOTE #3 TO OFFERORS: Stability testing will be required at various points during the production process. There is no single stability-indicating assay or parameter for all biological products. Therefore, manufacturers shall propose on a case-by-case basis stability-indicating profiles for their products which provide assurance that changes in identity, purity and potency of the product will be detected.

Reporting Requirements
HIV Vaccine Development Resources
RFP DAID-02-07

In addition to those reports required by the Statement of Work and other terms of this Contract the Contractor shall prepare and submit the following reports in the manner stated below. Reports will be required for Contractors with active Task Orders throughout the period of work.

I. Milestone Reports (each task order will include guidelines for milestone reports).

Upon the completion of each milestone as indicated in the Task Order, the Contractor shall submit three (3) paper copies of a milestone report as described below. Two (2) copies should be submitted to the Project Officer and one (1) copy to the Contracting Officer. Milestone reports must be submitted at least once per quarter even if no activity occurs during that period. The milestone report should be factual and concise and consist of the following:

a. A title page containing:

(a) Contract number and title
(b) Sequence of report; e.g., "Year 1, 2nd Milestone Report"
(c) Period of performance being reported
(d) Contractor's name and address
(e) Date of submission

b. Reports shall include, but are not limited to the following information:

(a) A report detailing the actions taken to achieve the milestone
(b) A report of all products, procedures and outcomes achieved
(c) Graphs and tables of data obtained
(d) A detailed budget report with invoices and cost justifications related to achieving this milestone
(e) Other information as may be required by the Project Officer

II. Final Report

The Contractor shall submit three (3) copies of the final report documents, two (2) copies to the Project Officer and one (1) copy to the Contracting Officer, which will summarize the results of the entire Task Order for the complete performance period. This report will be in sufficient detail to explain comprehensively the results achieved and will be submitted no later than the completion date of the Task Order.

The final report shall contain:

1) Title Page as described above in paragraph I.1(a)

2) Introduction covering the purpose and scope of the Task Order effort

3) Description of the overall progress, plus a separate description of each protocol and subcontract, protocol or assay employed and its modifications and performance on the Task Order during the period of performance. Descriptions will include pertinent data in tables or graphs as appropriate to present significant results achieved, conclusions resulting from analysis, and a scientific evaluation of the data accrued under the Task Order.

4) Copies of any abstracts, manuscripts, and publications

III. Other Deliverables

1) The Contractor, at the request of the Project Officer, shall deliver to the Government or its designee by the completion date of the Task Order, the following items:

(a) Test lots of vaccine products, as they are produced
(b) cGMP quality pilot lots of candidate vaccine products and adjuvants, as they are produced
(c) All vaccine Candidates and adjuvants in various stages of production at termination of the Task Order with detailed information on them
(d) A compete listing of accurate and updated information on design, development and production including activities of the Contractor, computerized data files, original data and any necessary information related thereto
(e) A complete list of accurate and updated information on activities of subcontracts
(f) Labeled and inventoried paper files
(g) Government-owned equipment and property

IV. If the Contractor becomes unable to deliver the reports or other deliverables within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons therefore at the address given below in section VII.

V. Copies of the technical reports shall be submitted as follows:

Type of Report	No. of Copies	Address:
Milestone	2	Project Officer
Final	2	PRDB, VPRP, NIAID, NIH Room 4106 6700-B Rockledge Drive MSC 7628 Bethesda, MD 20892-7628
Milestone	1	Contracting Officer
Final	1	CMB, DEA, NIAID, NIH Room 2230 6700-B Rockledge Drive Bethesda, MD 20892-7612

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm

[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

BECAUSE THIS IS A STREAMLINED RFP, ARTICLES I.2. AND I.3., WHICH IDENTIFY ANY AUTHORIZED ADDITIONS, SUBSTITUTIONS AND/OR MODIFICATIONS TO THE GENERAL CLAUSES, WILL BE BASED ON THE TYPE OF CONTRACT/CONTRACTOR AND WILL BE DETERMINED DURING NEGOTIATIONS.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this URL: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

FAR Clause No.	Date	Title
52.202-1	Oct 1995	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Mar 2000	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee

52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Oct 2000	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
52.223-6	Jan 1997	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	Feb 2000	Buy American Act - Balance of Payments Program – Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Jun 1997	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	Oct 1995	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs

52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR Clause No.	Date	Title
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – Rev. 02/2001]

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS **(Attached to this listing)**

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: May 25, 2001] **(Attached to this listing)**

[NOTE: Your attention is directed to the "proposal intent response sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

ELECTRONIC PROPOSAL SUBMISSION: Detailed information regarding the electronic process for submission of proposals may be accessed through the CMB Homepage at the following website by clicking on "E-Proposals".

http://www.niaid.nih.gov/contract/default.htm

PAGE LIMITATIONS:

THE NARRATIVE PORTION OF THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 50 PAGES. APPENDICES, ATTACHMENTS, OPERATING MANUALS, NON-SCANNABLE FIGURES OR DATA, LETTERS OF INTENT, ETC., SHALL NOT EXCEED 100 PAGES. CURRICULUM VITAEs (CVs) SHALL NOT EXCEED 5 PAGES (EACH).

OFFERORS ARE ENCOURAGED TO LIMIT THE OVERALL SIZE OF THE TECHNICAL PROPOSAL (EXCLUDING APPENDICES, ATTACHMENTS, OPERATING MANUALS, NON-SCANNABLE FIGURES OR DATA, LETTERS OF COLLABORATION/INTENT, ETC.). NOTE THAT ALTHOUGH NO PAGE LIMIT HAS BEEN PLACED ON THE BUSINESS PROPOSAL, OFFERORS ARE ENCOURAGED TO LIMIT ITS CONTENT TO ONLY THOSE DOCUMENTS NECESSARY TO PROVIDE ADEQUATE SUPPORT FOR THE PROPOSED COSTS.

TYPE DENSITY AND SIZE MUST BE 10 TO 12 POINTS. IF CONSTANT SPACING IS USED, THERE SHOULD BE NO MORE THAN 15 CPI, WHEREAS PROPORTIONAL SPACING SHOULD PROVIDE AN AVERAGE OF NO MORE THAN 15 CPI. THERE MUST BE NO MORE THAN SIX LINES OF TEXT WITHIN A VERTICAL INCH. MARGINS MUST BE SET TO 1 INCH AROUND.

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

http://www.niaid.nih.gov/contract/ref.htm

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **Technical Proposal Cover Sheet**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Government Notice for Handling Proposals**

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- **NIH-2043, Proposal Summary and Data Record**
- **Small Business Subcontracting Plan Format *[if applicable]***
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contact**

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Report of Government Owned, Contractor Held Property**
- **Disclosure of Lobbying Activities, OMB Form LLL**

PACKAGING AND DELIVERY OF THE PROPOSAL

[NOTE TO OFFEROR: Listed below are delivery instructions for the submission of the PAPER copies of your proposal. Instructions for your electronic submission are described above in Electronic Submission Instructions.]

Shipment and marking shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DAIDS-02-07
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and 5 unbound copies, with 10 copies of items excluded from electronic submission requirement that you choose to provide in paper format (SOPs, PERTINENT MANUALS, NONSCANNABLE FIGURES OR DATA, AND LETTERS OF COLLABORATION/INTENT.)

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES TO:

If hand delivery or express service	If using U.S. Postal Service
Janet M. Mattson Contracting Officer Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Janet M. Mattson Contracting Officer Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with PHSAR 352.215-10, Late Proposals, Modifications of Proposals and Withdrawals of Proposals (NOV 1986).

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-02-07
RFP Title: HIV Vaccine Production Resources

Please review the attached Request for Proposal. Furnish the information requested below and return this page by .May 25, 2001. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Janet M. Mattson
RFP-NIH-NIAID-DAIDS-02-07
FAX# (301) 480-5253
Email : jm32u@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.nci.nih.gov/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (February 2000)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*" or "*written*" means any worded or numbered expression which can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular

circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. **NAICS CODE AND SIZE STANDARD**

(1) The North American Industry Classification System (NAICS) code for this acquisition is 54171 .
(2) The small business size standard is 500 employees .

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS**

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

d. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that MULTIPLE AWARD(S) will be made from this solicitation and that the award(s) will be made on/about February 1, 2002 .

It is anticipated that the award(s) from this solicitation will be INDEFINITE DELIVERY/INDEFINITE QUANTITY contract(s) with COST REIMBURSEMENT, COMPLETION type Task Orders issued over a PERIOD OF PERFORMANCE OF FOUR YEARS and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

f. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

g. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

h. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

i. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

j. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

k. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that an Indefinite Delivery/Indefinite Quantity contract with cost-reimbursement (completion) type Task Orders will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However,

the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Care of Live Vertebrate Animals**

The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane

Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

(10) **Privacy Act**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(11) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily.

(12) **Small Business Subcontracting Plan**

In accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR. 52.219-9, incorporated herein by reference, for those concerns other than small business concerns, subcontracting plans will be required when the cumulative dollar amount for tasks issued against the contract exceed $500,000 in accordance with P.L. 95-507. The small, small disadvantaged, and women owned business subcontracting plans will have to reflect goals that allow the maximum practicable subcontracting opportunities retroactive to day one of the effective date of the contract. As subsequent tasks may be issued against the contract once small, small disadvantaged, and women owned business subcontracting goals have been established, the subcontracting goals will be subject to modification with each subsequent task.

A sample subcontracting plan format is provided in the Solicitation, SECTION J, List of Attachments.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to small business concerns, small business concerns owned and controlled by socially and economically disadvantaged individuals, and women-owned small business concerns and that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small disadvantaged, women-owned, and HUBZone small business concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, and HUBZone Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to small, small disadvantaged, women-owned, and/or HUBZone small business concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with small, small disadvantaged, women-owned, and HUBZone small business concerns.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that small, small disadvantaged, women-owned, and HUBZone small business concerns have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate small, small disadvantaged, women-owned, and HUBZone small business concerns and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

(13) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(14) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at:
http://www.sba.gov/size/NAICS-cover-page.htm

The Department of Commerce website for the annual determination is:
http://www.arnet.gov/References/sdbadjustments.htm

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this

solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

***NOTE:** FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(15) **Reimbursement of Costs for Independent Research and Development Projects** (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(16) **Salary Rate Limitation in Fiscal Year 2001**

Offerors are advised that pursuant to P.L. 106-554, no NIH Fiscal Year 2001 (October 1, 2000 - September 30, 2001) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.).

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 106-554 applies only to Fiscal Year 2001 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to

this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 106-554 states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

***This rate may change periodically. For your information, the rate can be found at: http://www3.opm.gov/oca/01tables/execses/html/01execsc.htm**

(17) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to

the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(18) **Solicitation Provisions Incorporated by Reference**, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

b) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

c) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

c. **BUSINESS PROPOSAL INSTRUCTIONS**

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(3) Qualifications of the Offeror

a) You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

(1) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

(2) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

(3) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

(4) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

(5) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(4) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

e) **Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)**

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(5) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(6) Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(7) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(8) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an Offeror for Contract award will be based on an evaluation of proposals against three (3) factors. The factors in order of importance are: (1) technical, (2) cost/price, and (3) Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the Contract, cost/price and SDB participation are also important to the overall Contract award decision.

In accordance with FAR 15.305, proposals will be subject to a cost realism analysis by the Government. Offerors are advised that an award will be made to that Offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be carefully evaluated. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed evaluation criteria listed below.

The technical evaluation criteria are used by the special emphasis panel when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes. Proposals will be judged solely on the written material provided by the Offerors.

2. MANDATORY QUALIFICATION CRITERIA

The following mandatory qualification criterion establishes conditions that MUST be met at the time of receipt of Final Proposal Revisions by the Contracting Officer in order for the proposal to be considered for award:

The Offeror must document that they have available biosafety level 2 facilities of sufficient capacity for all laboratory procedures and assays employing live HIV, SIV, or SHIV isolates.

3. EVALUATION OF TARGETS FOR EXTENT OF SMALL DISADVANTAGED BUSINESS (SDB) PARTICIPATION

SDB participation will not be scored, but the Government's conclusion about overall commitment and realism of the offeror's SDB participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's SDB Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

1) The extent of participation of SDB concerns in terms of the value of the total acquisition.

2) The complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.

4. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERA	Subweight	WEIGHT
A. Technical Approach: Overall understanding of the project, and adequacy and feasibility of plans to address all items in the Work Statement. This includes the detailed description of specific tasks to be performed, methods to be used, and discussion of problems likely to occur and plans for addressing them. Reviewers will carefully evaluate the lines of authority, operational plans, and plans for decision making.		**(40 Points)**
A.1. Vaccine development and production: Adequacy of the technical approach for preparing experimental vaccines, as requested in the Statement of Work, including soundness of sample protocol, adequacy of scale-up and production under GLP/cGMP procedures, packaging and formulation, safety, logistics, and coordination.	**(30 Points)**	
A.2. Plan for performance of vaccine lot characterization tests (lot release testing): Technical approach for assessing potency, safety, sterility, purity, identity, quantity and stability including logistics, coordination and preparations for IND submissions.	**(10 Points)**	
B. Experience and Qualification of Personnel		**(35 Points)**
B.1. Documented expertise and proficiency of the Principal Investigator in (1) development and pilot lot production of vaccines for use in human clinical trials; (2) in managing a project of comparable size and complexity; and (3) documented availability (percent effort)	**(15 Points)**	
B.2. Documented expertise and proficiency of other professional and technical staff in (1) development and production of vaccine products and (2) documented availability (percent effort)	**(10 Points)**	
C. Facilities and Resources Availability of adequate facilities, equipment and resources necessary to safely and efficiently accomplish the work described in the Statement of Work. Adequacy of detailed floor plan, indicating space to be committed for performance of this project.		**(15 Points)**

D. Flexibility Capability and willingness to produce a variety of different products within a vaccine Category as opposed to making only a single proprietary product.		**(10 Points)**
TOTAL POINTS		**(100 Points)**